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October 22, 2007

U.S. Nuclear Regulatory Commission
Region III
Materials Licensing Branch
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

Dear Reader:

Re: NRC License Number 24-00128-03

This is to notify you, in accordance with 10 CFR 35.14, that Paul H. Holcomb, Jr, M.D. has begun work as an authorized user under our license for uses under 10 CFR 35.100 and 35.200 (excluding generators and Xenon-133 and limited to cardiovascular imaging procedures).

Dr. Holcomb is an authorized user on the Ohio Radioactive Material License of Cardiovascular Consultants of Cleveland, Inc., License No. 02201180008. He is authorized for uses specified in Ohio Administrative Code that are equivalent to those in 10 CFR 35.100 and 35.200 (excluding generators and Xenon-133 and limited to cardiovascular imaging procedures). Enclosed are copies of the license and relevant sections of the Illinois Administrative Code.

If you have any questions regarding this notification, please feel free to call me at 573-651-5544.

Sincerely,

Sam S. Hancock, Ph.D.
Radiation Safety Officer

Enclosures: Copy of Ohio license no. 02201180008
Relevant part of Ohio Administrative Code

cc: Pat Bira, Vice President
Mark Gates, M.D., Chairman, Radiation Safety Committee

1701 Lacey Street • Cape Girardeau, MO 63701 • 1-800-455-4636
Radiation Oncology 573/651-5544 • Outpatient Chemotherapy 573/651-5550

RECEIVED OCT 25 2007

Amendment No. 11

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OHIO DEPARTMENT OF HEALTH LICENSE FOR RADIOACTIVE MATERIAL

Pursuant to Chapter 3748 of the Ohio Revised Code, and in reliance on statements and representations made by the licensee, a license is hereby issued authorizing the licensee named herein to receive, acquire, possess, and transfer radioactive material as designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the applications of Chapter 3748 of the Ohio Revised Code and all applicable rules promulgated thereunder. This license is subject to all applicable rules, regulations and orders of the Ohio Department of Health now or hereinafter in effect and to any conditions specified below.

1. Cardiovascular Consultants of Cleveland, Inc. 2. 730 SOM Center Road Mayfield Village, Ohio 44143	LICENSEE	LICENSE NUMBER
		3. 02201180008
		EXPIRATION DATE
		4. May 1, 2009
		BUREAU DOCKET NUMBER
		5. AC31-06-98

6. RADIOACTIVE MATERIAL	7. CHEMICAL AND/OR PHYSICAL FORM	8. MAXIMUM QUANTITY THAT LICENSEE MAY POSSESS AT ANY ONE TIME UNDER THIS LICENSE
A. Any radioactive material identified in rule 3701:1-58-32 of the Ohio Administrative Code	A. Any radiopharmaceutical form	A. As needed, not to exceed 3.7 GBq (100 mCi) of Cobalt-57
B. Any radioactive material identified in rule 3701:1-58-34 of the Ohio Administrative Code	B. Any radiopharmaceutical form	B. As needed
C. Cobalt - 57	C. Sealed source	C. As needed, no single source to exceed 555 MBq (15 mCi)

9. Authorized Use
- A. Uptake, dilution and excretion studies per rule 3701:1-58-32 of the Ohio Administrative Code.
 - B. Diagnostic Imaging and Localization per rule 3701:1-58-34 of the Ohio Administrative Code.
 - C. Check, calibration, and reference sources.

CONDITIONS

10. Licensed material may only be used at the licensee's facilities located at:
- | | |
|--|---|
| A. 730 SOM Center Road
Mayfield Village, Ohio 44143 | B. 36100 Euclid Avenue, Suite 300
Willoughby, Ohio 44094 |
|--|---|
11. The Radiation Safety Officer or Person in Charge of the radioactive material for this license is:
James K. O'Donnell, M.D.

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12. Licensed material is only authorized for use by, or under the supervision of:

Individuals permitted to work as an authorized user, authorized nuclear pharmacist, and / or authorized medical physicist in accordance with rule 3701:1-58-08 and 3701:1-58-09 of the Ohio Administrative Code.

The following individuals are authorized users for the material and medical uses indicated:

Authorized User	Material and Uses
A. Kondaanar C. Guruprasad, M.D.	A. Use permitted by rule 3701:1-58-32 of the Ohio Administrative Code, limited to cardiovascular imaging procedures.
B. James K. O'Donnell, M.D.	B. Use permitted by rule 3701:1-58-34 of the Ohio Administrative Code.
C. Paul H. Holcomb, M.D.	C. Uses permitted by rules 3701:1-58-32 and 3701:1-58-34 of the Ohio Administrative Code, (excluding generators and Xenon-133 and limited to cardiovascular imaging procedures).

13. All persons performing activities meeting the definition of "Nuclear Medicine Technologists" as specified in R.C. 4773.01 shall be licensed and in good standing with the State of Ohio.

14. All sealed sources that are used or obtained shall have been evaluated and approved under the provisions of rule 3701:1-46-49 of the Ohio Administrative Code or by equivalent NRC, Agreement State, or NARM licensing state regulation.

15. In addition to the requirements by rule 3701:1-58-38 of the Ohio Administrative Code, any patient administered gamma emitting radiopharmaceuticals or permanent brachytherapy sources shall be provided a patient release card to include:

- (1) The patient's name.
- (2) The radionuclide administered and its activity.
- (3) The facility name which administered the radionuclide.
- (4) The date of the administration of the radionuclide.
- (5) The expiration date of the card.

The card is not applicable to those patients who are institutionalized (Hospitals, Nursing Homes, Correctional Institutions, etc.) or whose radiation levels do not exceed 0.1 mR/hr at one meter.

16. In addition to the possession limits in Item 5, the licensee shall further restrict the possession of sealed source licensed material to quantities below the maximum limit specified in rule 3701:1-40-17(C) of the Ohio Administrative Code for establishing decommissioning financial assurance.

17. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The Ohio Department of Health's statutes, rules, and orders shall govern unless statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

- A. Renewal application dated April 1, 2004;
- B. Amendment #7 of License 02201180008; renewed in its entirety
- C. Letter dated March 9, 2005 (Amendment 8)
- D. Letter dated August 3, 2005 (Amendment 9)
- E. Letter dated December 2, 2005 (Amendment 10)
- F. Director's Order signed April 21, 2006 (Amendment 11)

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For the Ohio Department of Health

DATE:

6/12/06

BY:

Director, Ohio Department of Health

Route:

- **Ohio Administrative Code**
- **» 3701:1 Radiation Control**

Chapter 3701:1-58 Medical Use of Radioactive Materials

3701:1-58-32 Use of unsealed radioactive material for uptake, dilution, and excretion studies for which a written directive is not required.

Except for quantities that require a written directive under paragraph (B) of rule 3701:1-58-15 of the Administrative Code, a licensee may use any unsealed radioactive material prepared for medical use for uptake, dilution, or excretion studies that is:

(A) Obtained from a manufacturer or preparer licensed under rule 3701:1-46-43 of the Administrative Code or equivalent United States nuclear regulatory commission, agreement state, or NARM licensing state for NARM requirements;

(B) Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in rules 3701:1-58-36 or 3701:1-58-40 of the Administrative Code, or an individual under the supervision of either as specified in rule 3701:1-58-14 of the Administrative Code;

(C) Obtained from and prepared by an United States nuclear regulatory commission, agreement state, or NARM licensing state for NARM licensee for use in research in accordance with a radioactive drug research committee-approved protocol or an investigational new drug protocol accepted by United States food and drug administration; or

(D) Prepared by the licensee for use in research in accordance with a radioactive drug research committee-approved application or an investigational new drug protocol accepted by United States food and drug administration.

Effective: 08/15/2005

R.C. 119.032 review dates: 08/15/2010

Promulgated Under: 119.03

Statutory Authority: 3748.02, 3748.04

Rule Amplifies: 3748.04

3701:1-58-34 Use of unsealed radioactive material for imaging and localization studies for which a written directive is not required.

Except for quantities that require a written directive under paragraph (B) of rule 3701:1-58-15 of the Administrative Code, a licensee may use any unsealed radioactive material prepared for medical use for imaging and localization studies that is:

(A) Obtained from a manufacturer or preparer licensed under rule 3701:1-46-43 of the Administrative Code or equivalent United States nuclear regulatory commission, agreement state, or NARM licensing state for NARM requirements;

(B) Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in rules 3701:1-58-36 or 3701:1-58-40 of the Administrative Code, or an individual under the supervision of either as specified in rule 3701:1-58-14 of the Administrative Code;

(C) Obtained from and prepared by an United States nuclear regulatory commission, agreement state, or NARM licensing state for NARM licensee for use in research in accordance with a radioactive drug research committee-approved protocol or an investigational new drug protocol accepted by United States food and drug administration; or

(D) Prepared by the licensee for use in research in accordance with a radioactive drug research committee-approved application or an investigational new drug protocol accepted by United States food and drug administration.

Effective: 08/15/2005

R.C. 119.032 review dates: 08/15/2010

Promulgated Under: 119.03

Statutory Authority: 3748.02, 3748.04

Rule Amplifies: 3748.04

*** Southeast Missouri Hospital**
Regional Cancer Center

1701 Lacey Street
Cape Girardeau, MO 63701
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2443 WARRENVILLE ROAD, SUITE 210
LISLE, IL 60532-4352

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